REMARKS

Claims 1-38, 40-42, 44-48, 52-57, 59, 61, 64-68 and 70 were previously cancelled. Claims 60, 71 and 72 are currently cancelled. Applicants reserve the right to file continuing applications directed to the cancelled subject matter. Claims 39, 49, 58, 62, 69 and 73 are currently amended. Support for the amendments can be found throughout the specification, particularly in the claims as originally filed. No new matter has been added. Claims 39, 43, 49-51, 58, 62, 63, 69, 73 and 74 are currently under consideration.

Rejection Under 35 U.S.C. §112, First Paragraph--Enablement

Claims 39, 43, 49-51, 58, 60-63, 69, and 71-74 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that the specification "...while being enabling for use of *Tupaia belangeri* infected with HIV-1 or HBV in the claimed method for developing a therapeutic procedure, does not reasonably provide enablement for the use of any *Tupaia* species or for other human pathogens." Office Action page 3.

35 U.S.C. §112, first paragraph, requires that a specification enable one skilled in the art to make and use the claimed invention. A specification fails to meet this requirement if the specification fails to provide sufficient information regarding the claimed subject matter to enable a skilled artisan to make and use the claimed invention. "However, to comply with 35 U.S.C. §112, first paragraph, it is not necessary to 'enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.' CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003)." (MPEP §2164). To determine if sufficient information is provided, one must inquire whether the claimed invention can be practiced without undue experimentation. MPEP §2164.01. That some experimentation may be required is not fatal because the issue is whether the experimentation is undue. In re Vaeck, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Applicants respectfully disagree with the Examiner's rejection and assert that the claims are fully enabled. However, solely in an effort to promote prosecution, claims 39, 49, 58 and 69

have been amended to recite the use of *Tupaia belangeri* species. In addition, claims 58 and 69 have been amended to recite that the human viral pathogen is HCV, HIV 1 or HIV 2. All of the claims are now limited to *Tupaia belangeri* and the human viral pathogen HBV, HCV, HIV 1 or HIV 2.

The Examiner states that the claims cover any *Tupaia* species infected with any human viral pathogen. Office Action page 4. Applicants respectfully assert that this statement is overdrawn. The list of viruses encompassed by the claim language is narrower than what is asserted by the Examiner. For instance, the claims are now limited to HCV, HBV (dependent claims), HIV 1 or HIV 2. Therefore, only a subset of human viral pathogens is covered by the claims. With regards to HCV, Applicants once again assert that it was known in 1998 that HCV could infect *Tupaia* (Xie *et al.*, 1998 Virology 244 513-520; Applicants file concurrently with this amendment a copy of Xie *et al.* for the Examiner's convenience). The specification clearly describes methods for determining susceptibility to HBV, as acknowledged by the Examiner in the Office Action. The specification also describes support for the use of HIV in the methods of the invention. As quoted above, the Examiner clearly acknowledges that the specification is enabled for HIV. Office Action page 3. Thus, methods to evaluate susceptibility of *Tupaia belangeri* to infection by a given viral pathogen are well understood by one skilled in the art. The same receptors (CCR5 and CXCR4) are present on both HIV 1 and HIV 2 (Hill *et al.*, 1997 J Vir 71; 6296-6304) such that successful infection by HIV 1 indicates that HIV 2 will also be capable of infection by *Tupaia belangeri.*

Therefore, Applicants respectfully contend that the claims as currently amended, drawn to a method for developing a procedure in an animal system comprising infecting *Tupaia belangeri* with a human viral pathogen wherein the pathogen is HBV, HCV, HIV 1 or HIV 2 are fully enabled by the present specification. As discussed above, "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). Withdrawal of the rejection of claims 39, 43, 49-51, 58, 60-63, 69, and 71-74 is respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph—Written Description

Claims 39, 43, 49-51, 58, 60-63, 69 and 71-74 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that:

> The claims are directed to the use of a *Tupaia* species as an animal model for infection with a human viral pathogen and methods for developing a therapeutic procedure.
>
> The claims encompass the use of any *Tupaia* species as a model for any human viral pathogen in the claimed methods. However, the specification only discloses two animal model systems.

Office Action page 6.

Under 35 U.S.C. §112, first paragraph, a specification must describe the invention with sufficient detail so that one of ordinary skill in the art would conclude that the inventor had possession of the claimed invention. MPEP (Rev. 6, Sept. 2007) §2163; *Lockwood v. American Airlines, Inc.,* 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997).

Generally, "there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. [Citation omitted]." MPEP §2163. It is the Patent Office's burden to overcome this presumption and establish that one skilled in the art would not recognize that the inventor had possession of the claimed invention because, for example, the recited elements that are not conventional in the art or known to one of ordinary skill in the art and are not described in the specification. MPEP §2163; *In re Alton*, 76 F.3d 1168, 1175-76 (Fed. Cir. 1996) (holding that the Patent Office, "must provide reasons why one of ordinary skill in the art would not consider the description sufficient.").

Applicants respectfully disagree with the Examiner's assertion that the claims are directed to the use of *Tupaia* in "any human viral pathogen". As discussed previously, claims 39, 49, 58 and 69 have been amended to recite the use of *Tupaia belangeri* species. In addition, claims 58 and 69 have been amended to recite that the human viral pathogen is HCV, HIV 1 or HIV 2, and dependent claims are limited to HBV. Thus, the claims are now limited to *Tupaia belangeri* and the human viral pathogen HBV, HCV, HIV 1 or HIV 2.

The Examiner cites to a wide variety of human viral pathogens on page 6 of the Office

Action. However, most of the cited pathogens are not applicable to the subject matter of claims 39, 49, 58, and 69, which are now limited to HCV, HIV 1, and HIV 2.

On pages 6 and 7 of the Office Action, the Examiner states that "The instant specification only deals with two viral pathogens and their infectivity on a single species of Tupaia." As discussed above, HIV-2 can utilize the same receptors as HIV-1 such that successful infection by HIV-1 makes it highly likely that HIV-2 will also share this same characteristic. It was known in that art at the time of filing the instant application that HCV can infect *Tupaia*. See Xio reference, cited above. However, it was not known whether HCV infection of *Tupaia* duplicated secondary manifestations that are the hallmark of human infection by both HBV and HCV. The parallels between the HBV and HCV self-destructive immune responses in humans make it very likely that this would continue to be paralleled in *Tupaia* infections and, as such, it has been predicted that HCV would have secondary disease manifestations.

The Examiner further states that "The specification does not disclose any process developed or derived from any animal model as set forth in the claims." Office Action page 7. Contrary to the Examiner's assertions, Example 2 specifically describes a therapeutic process (oral tolerization) that was developed using *Tupaia* as an animal model. Decreases in secondary disease manifestations were noted and commented upon in this Example. The present application teaches the use of an animal model that would be suitable for procedures to be developed by the user. Once given this tool, one skilled in the art would have the ability to use this tool.

The Examiner acknowledges on page 9 of the Office Action that human disease symptoms would be known for a given viral pathogen, but then states that it would be unknown which pathogen would be held in common with infection of *Tupaia*. Ascertaining particular manifestations in the *Tupaia* model would simply require adaptation of the same tests used in humans, thus incurring the use of standard tests. The viral pathogens influenza, measles and mumps are not encompassed by the current claims as they are not HBV, HCV, HIV 1, or HIV 2 as required by the currently amended claims.

The amended claims are clearly described in the specification such that one of skill in the art would conclude that Applicants had possession of the claimed invention. Applicants

respectfully request withdrawal of the rejection of claims 39, 43, 49-51, 58, 60-63, 69 and 71-74.

CONCLUSION

Applicants respectfully submit that all claims are in condition for allowance. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel at the number listed below to resolve such issues and place all claims in condition for allowance.

The Office is hereby authorized to charge any additional fees or credit any overpayments under 37 C.F.R. § 1.16 or § 1.17 to the deposit account number 50-0525.

Respectfully submitted,

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